

CLAIMS

What is claimed is:

- Dep A37* ✓
- 5 1. A method of treating an inflammatory disorder, comprising administering a topical formulation of a pharmaceutical composition comprising a pharmaceutically effective amount of IL-11.
2. The method of claim 1 wherein the disorder is mucositis.
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3. The method of claim 2 wherein the mucositis is oral mucositis.
4. The method of claim 2 wherein the mucositis is gastrointestinal mucositis.
5. The method of claim 1 wherein the disorder is an inflammatory skin disorder.
- 10 6. The method of claim 5 wherein the inflammatory skin disorder is psoriasis.
7. The method of claim 1 wherein the disorder is necrotizing enterocolitis.
8. The method of claim 1 wherein the disorder is an ocular disease.
9. The method of claim 8 wherein the ocular disease is selected from the group consisting of conjunctivitis, retinitis and uveitis.
- 15 10. The method of claim 1 wherein the disorder is selected from the group consisting of aphthous ulcers, pharyngitis, esophagitis, peptic ulcers, gingivitis, and periodontitis.

11. The method of claim 1 wherein the pharmaceutically effect amount of IL-11 is between about 1 and about 250 $\mu\text{g/kg}$ body weight.
12. The method of claim 1, wherein the pharmaceutical composition comprises a solution containing IL-11 and a suitable liquid carrier.
- 5 13. The method of claim 12, wherein the suitable liquid carrier is selected from the group consisting of water, organic solvents, oils and fats.
14. The method of claim 12, wherein the suitable liquid carrier is sodium bicarbonate.
15. The method of claim 12, wherein the suitable liquid carrier is an infant formula.
- 10 16. The method of claim 1, wherein the pharmaceutical composition comprises an immediate release carrier for immediate release of IL-11 into the oral cavity.
17. The method of claim 16, wherein the immediate release carrier is selected from the group consisting of sugars, glycine, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, hydroxypropylmethyl cellulose, and sodium
15 carboxymethyl cellulose.
18. The method of claim 16, wherein the topical formulation is selected from the group consisting of an oral gel, tablet or suspension.
19. The method of claim 1, wherein the pharmaceutical composition comprises an immediate release carrier for delivery of IL-11 to the gastrointestinal tract.

20. The method of claim 19, wherein the immediate release carrier is selected from the group consisting of sugars, glycine, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, hydroxypropylmethyl cellulose, and sodium carboxymethyl cellulose.
- 5 21. The method of claim 19, wherein the topical formulation is a pill, tablet or capsule.
22. The method of claim 1, wherein the pharmaceutical composition comprises a sustained-release carrier for delivery of IL-11 to the oral cavity.
- 10 23. The method of claim 21, wherein the topical formulation is a patch, lozenge or an uncoated tablet.
24. The method of claim 1, wherein the pharmaceutical composition comprises a sustained-release carrier for delivery of IL-11 to the gastrointestinal tract.
25. The method of claim 24, wherein the topical formulation is a pill, tablet or capsule.
- 15 26. The method of claim 1, wherein the pharmaceutical composition comprises an immediate release carrier for delivery of IL-11 for cervical administration.
27. The method of claim 25, wherein the topical formulation is selected from the group consisting of a topical cream, solution, ointment, and gel.
- 20 28. The method of claim 1, wherein the pharmaceutical composition comprises a sustained-release carrier for delivery of IL-11 for cervical administration.

-31-

29. The method of claim 26, wherein the topical formulation is a topical cream, solution, ointment or gel.
30. The method of claim 1, wherein the pharmaceutical composition comprises an enema preparation of IL-11 and a suitable liquid carrier for delivery to the colon.
- 5 31. The method of claim 1, wherein the pharmaceutical composition comprises a proteinase inhibitor.
32. The method of claim 31, wherein the proteinase inhibitor is selected from the group consisting of aprotinin, α -macroglobulin, soybean trypsin inhibitor, and ovomucoid.
- 10 33. The method of claim 31, wherein the proteinase inhibitor is aprotinin.
34. The method of claim 1, wherein the topical formulation comprises an enteric coating.
35. The method of claim 34, wherein the enteric coating is selected from the group consisting of a methacrylic acid-methacrylic acid ester-based copolymer, an anionic water-soluble polymer cellulose ether, cellulose acetate phthalate, 15 polyvinyl acetate phthalate, and hydroxypropyl methylcellulose phthalate.
- ~~36.~~ A composition for treating an inflammatory disorder, wherein said composition is a topical formulation comprising a pharmaceutically effective amount of IL- 20 11 and a suitable liquid carrier.

37. The composition of claim 36, wherein said suitable liquid carrier is sodium bicarbonate.
38. The composition of claim 36, wherein said suitable liquid carrier is an infant formula.
- 5 39. A composition for treating an inflammatory disorder, wherein said composition is a topical formulation comprising a pharmaceutically effective amount of IL-11 and a suitable solid carrier.
40. The composition of claim 39, wherein said suitable solid carrier is an immediate release carrier.
- 10 41. The composition of claim 40, wherein said immediate release carrier is selected from the group consisting of sugars, glycine, lactose, dextrin, starch, gelatin, cellulose, methyl cellulose, hydroxypropylmethyl cellulose, and sodium carboxymethyl cellulose.
- 15 42. The composition of claim 39, wherein said suitable solid carrier is a sustained-release carrier.
43. The composition of claim 39, wherein said suitable solid carrier comprises a proteinase inhibitor.
- 20 44. The composition of claim 39, wherein the proteinase inhibitor is selected from the group consisting of aprotinin, α -macroglobulin, soybean trypsin inhibitor, and ovomucoid.

45. The composition of claim 44, wherein the topical formulation comprises an enteric coating.
46. The composition of claim 45, wherein the enteric coating is selected from the group consisting of a methacrylic acid-methacrylic acid ester-based copolymer, an anionic water-soluble polymer cellulose ether, cellulose acetate phthalate, polyvinyl acetate phthalate, and hydroxypropyl methylcellulose phthalate.

5